REMARKS

Applicants have now had an opportunity to fully review the Office Action dated March 10, 2009. Applicants respond as follows:

Claims 1 and 3-11 are pending in this application.

Claims 1 and 3 are amended.

Claim 2 is cancelled.

New claims 8-11 are added. Support for new claims 8 and 9 are to be found on page 2 of the specification. Support for claims 10 and 11 are to be found in claim 1 and on pages 11-14 of the specification.

The Office Action

In the Office Action, it was noted that trademarks should be recognized and accompanied by appropriate generic terminology.

The disclosure was objected to for informalities.

Claim 3 was objected to for failure to be a complete sentence.

Claims 1-7 were rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement.

Claims 1 and 3-7 were rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the enablement requirement.

Claims 1-7 were rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the enablement requirement.

Claims 1-7 were rejected under 35 U.S.C. §102(b) as being anticipated by Sakurai, et al., *Polymer Preprints*, 45/2:457-458 (2004), or Mizu, et al., *J. Am. Chem. Soc.*, 126:8372-8373 (2004).

Claims 1-7 were rejected under 35 U.S.C. §102(a) as being anticipated by Anada, et al., *Trends in Glycoscience and Glycotechnology,* 17/94:49-57 (March 2005), or Sakurai, et al., *Non-Viral Gene Therapy,* Ed.: Taira, et al., pp. 103-117 (2005).

Claims 1-5 were rejected under 35 U.S.C. §102(b) as being anticipated by Sakurai, et al., 228th ACS National Meeting, August 22-26, 2004 (Abstract only).

For the reasons outlined below, it is submitted that the claims are in condition for allowance.

Statement of Substance of Interview

Applicants wish to thank the Examiner for the courtesy of a telephone interview on March 23, 2009, in which the Examiner agreed to take note that certain sequence IDs are provided in the specification, specifically SEQ. ID. Nos. 5 and 6 on pages 30 and 31. The Examiner also provided guidance on overcoming the §112 rejections, which is appreciated by Applicants.

Objections

The specification has been amended to recognize trademarks, which are accompanied by appropriate generic terminology. A typographical error on page 24 has been corrected by replacing Gel Ster with GELSTAR.

FIGURE 2 and the specification at pages 2, 16, and 26 have been amended to identify sequence IDs for oligonucleotide sequences. The sequence named SEQ ID No. 2 on page 26 has been labeled SEQ ID No. 18. Applicants note that SEQ. ID. Nos. 5 and 6 on pages 30 and 31 are listed, after a brief description of the respective sequence has been provided.

The current address of the ATCC has been added in Example 1.

Claim 3 has been amended by inserting a period at the end.

Accordingly, it is requested that the objections to the specification, drawings, and claims be withdrawn.

35 U.S.C. §112, First Paragraph Rejections

Claim 1 has been amended to recite that the immunostimulating oligonucleotide contains an unmethylated CpG motif, as recited in original claim 2, now cancelled. Claim 1 has been further amended to recite the immunostimulating oligonucleotide being of 8 to 100 nucleotides. Support for this amendment are found on page 2, line 8, of the specification.

Applicants submit that the claims now meet the requirements for both the written description requirement and enablement requirements.

As the Examiner will appreciate, the exact chemical structure of the complex is not known, nor is it necessary for an exact structure to be provided for the written description requirement to be met where identifying characteristics, such as those

shown in FIGURE 4, and properties of the complex and comparative examples, shown in FIGURES 5-19, provide evidence that Applicant was in possession of the invention.

Nor is there a requirement for a biological sample to be placed on deposit, since such a requirement of deposit for biological materials is usually only applicable to materials which are self replicating. Moreover, such a deposit requirement is not necessary in this case because it would have been obvious to one of ordinary skill in the art, based on a full reading of the specification, how to generate the agent based on the described methods.

The immunostimulating agents of the present invention are well suited to use for humans. It has been shown that a CpG motif which is elective to mice will be effective to humans as well. AGCGTT is listed among the CpG motifs on page 2 of the present specification and is shown to be effective in both mice and humans. See, for example, Dennis M. Klinman, et al., Proc. Natl. Acad. Sci. USA, Vol. 93, pp. 2879-2883, April 1996; and Mayda Gürsel, et al., J. Leukocyte Biology, Vol. 71, pp. 813-821, May 2002, copies of which are submitted herewith. Klinman, et al. relates to immunostimulation experiments with mouse cells. The sequence employed is denoted as A3 which contains AGCGTT at the later part thereof (Table 1, p. 2880). CpG ONDs demonstrate increased amounts in the production of various cytokines from BALB/c mice spleen cells, as compared with A6 (control): As noted on page 2881, "pODNs containing the dinucleotide CpG consistently triggered cytokine release (see ODNs A1, A2, A3, Table 1), whereas pODNs lacking this motif (A6) did not. Multiple CpGs generally resulted in greater stimulatory capacity (Table 1, compare pODN A1 with A3), although CpGs located at the terminus of an ODN were ineffective (A4, A5)."

Gürsel, et al., relates to immunostimulation experiments with human cells. The sequence employed is denoted as K23 containing AGCGTT at the middle part thereof (page 813, right column, the second paragraph). K23 ("K") demonstrates increased amounts in the production of various cytokines from human peripheral blood mononuclear cells (PBMC), as compared with "K" control: Table 1 (page 815). At page 815, left column it states " "K" ODN also triggered a greater than tenfold increase in B-cell proliferation ($P<0.05$), a greater than tenfold increase in IgM production ($P<0.1$), and a fivefold increase in the number of B cells secreting IL-6 ($P<0.001$)."

Accordingly, it is requested that §112, first paragraph, rejections be withdrawn.

§102 Rejections

Applicants submit herewith a certified translation of JP priority application (JP 2003-136876, filed May 15, 2003). The parent application discloses the subject matter of the claimed immunostimulating agent and was filed before the publication of the cited references (Sakurai, et al., Polymer Preprints 45/2:457-458(2004); Mizu, et al., J. Am. Chem. Soc. 126:8372-8373 (2004); Anada, et al., Trends in Glycoscience and Glycotechnology, 17/94:49-57 (March 2005); Sakurai, et al., Non-viral Gene Therapy, pp 103-117 (2005); Sakurai, et al., (Abstract) 228th ACS National meeting, August 22-26 (2004)). For the Examiner's reference, this priority application substantially corresponds to the parent PCT Application (and therefore the present U.S. Application), except that the latter additionally includes descriptions at line 24, page 11 through the first paragraph, page 14, and Examples 12, 13, and 14, comparative Examples 2, 3, and 4 (page 27 through page 32), and Figures 8 through 19. Accordingly, it is respectfully requested that the §102 rejections of claims 1-7 be withdrawn.

CONCLUSION

For the reasons detailed above, it is respectfully submitted all claims remaining in the application (Claims 1 and 3-22) are now in condition for allowance.

☒ Remaining Claims, as delineated below:

(1) FOR	(2) CLAIMS REMAINING AFTER AMENDMENT LESS HIGHEST NUMBER PREVIOUSLY PAID FOR		(3) NUMBER EXTRA
TOTAL CLAIMS	10	- 20=	0
INDEPENDENT CLAIMS	2	- 3=	0

Respectfully submitted,

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July 10, 2009
Date

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